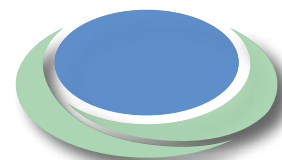


Single Use Filshie Clip System

Female Surgical Contraception

The Best Just Got Better!

A truly innovative applicator,
providing even greater convenience...



FEMCARE-NIKOMED

A FEMCARE GROUP COMPANY



**Beautifully
Simple...**



First choice by leading Clinicians around the world...

Since its launch in 1982, the Filshie Clip System has become accepted as the “Gold Standard” for female surgical contraception by leading surgeons around the globe. Over 8 million Filshie Clips have been successfully applied worldwide.

Gynaecologists have come to rely on the Filshie Clip System for two simple reasons:

1) Excellent Clinical Results

The Filshie Clip System has demonstrated a success rate of 99.76%⁽⁴⁾ making it an extremely effective method for female surgical contraception. Studies from around the world have consistently shown low failure rates of the Filshie Clip. The table below highlights some of these results:

Investigator	Patients (No.)	Follow-up (Yrs)	Failures (No.)	Failure Rate (%)
Filshie	434	6-15	1	0.23
Heslip	467	10	1	0.21
Yuzpe (Rioux et al)	497	10	0	0
Puraviappan et al	796	7	3	0.37
Kovacs & Krins ⁽⁴⁾	30,000	5	73	0.24

Although not available in the USA when the CREST study was conducted, additional long-term follow-up studies of the Filshie Clip confirm its enviably low failure rate.

The Crest 10-year follow-up study⁽¹⁾ indicates the following failure rates for comparative methods:

Method	Patients (No.)	Failure Rate (%)
Bi-Polar	2,267	2.48
Yoon Ring/Falope Ring	3,329	1.77
Hulka Clip	1,595	3.65

2) Reduced Risk of Ectopic Pregnancy

The ectopic pregnancy rate in the rare event of a Filshie Clip failure is just 4%⁽⁹⁾. This compares most favourably with modern contraceptive methods such as the IUS, where ectopic rates can be 1 in 20⁽⁸⁾.

The simplicity and reliability of the system have made the Filshie Clip a truly world class product. The Royal College of Obstetricians and Gynaecologists Evidence-based Clinical Guideline Number 4, Male and Female Sterilisation⁽⁵⁾, recommends “Mechanical occlusion of the tubes by Filshie Clips or Rings as the method of choice for laparoscopic tubal occlusion”.



Totally simple but now totally disposable...

The “Gold Standard” of surgical contraception has now been improved with the launch of the Single Use Filshie Kit, offering even greater convenience for the surgeon and patient:

Fully compatible. . .

- ✓ The Single Use Filshie Kit is fully compatible with the existing Filshie Clip. It uses the same reliable Clip closure mechanism and no major change in technique is required.

Fully disposable. . .

- ✓ Designed for single patient use, the Single Use Filshie Kit ensures that every clip is closed by a precisely calibrated applicator.

Greater convenience. . .

- ✓ The Single Use Filshie Kit is always available “off-the-shelf” whenever you have a case and eliminates the need for post-surgical cleaning and reprocessing.

Cost efficient. . .

- ✓ The Single Use Filshie Kit delivers significant cost savings – an end to cleaning, sterilising, servicing and re-calibration charges and reduced capital inventory costs.

Femcare-Nikomed offers the Single Use Filshie Kit in the following formats:

1) The ‘Standard’ Kit:

A convenient and simple entry-level kit comprising:

- One Single Use Filshie Clip Applicator
- One pair of Filshie Clips

2) The ‘Premium’ Kit:

A procedural kit comprising:

- One Single Use Filshie Clip Applicator
- One pair of Filshie Clips
- One Femcare-Nikomed Disposable **Un-shielded** Trocar and Cannula, specifically designed for use with the Single Use Filshie Clip Applicator

3) The ‘Elite’ Kit:

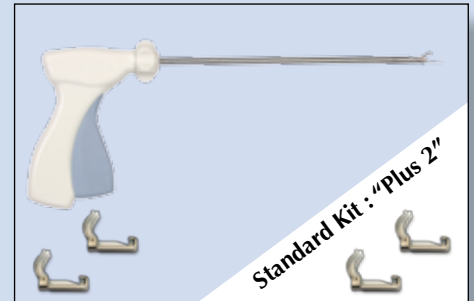
A procedural kit comprising:

- One Single Use Filshie Clip Applicator
- One pair of Filshie Clips
- One Femcare-Nikomed Disposable **Shielded** Trocar and Cannula

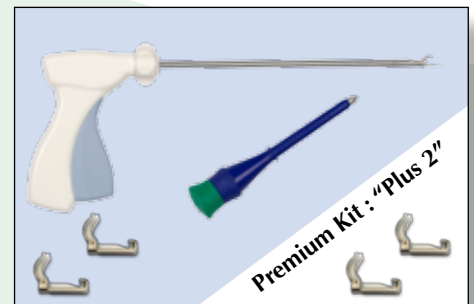
4) The “Plus 2” Series:

The “Plus 2” Series offers the user the option of buying either a Standard, Premium or Elite Single Use Filshie Kit with two sterile pairs of Filshie Clips.

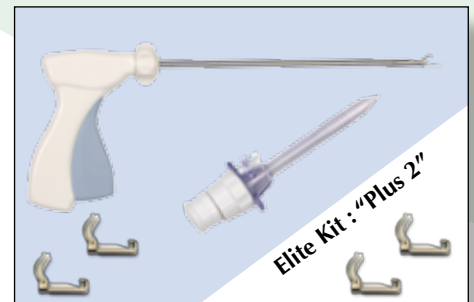
Kit 1: Single Use Filshie Kit - Standard



Kit 2: Single Use Filshie Kit - Premium

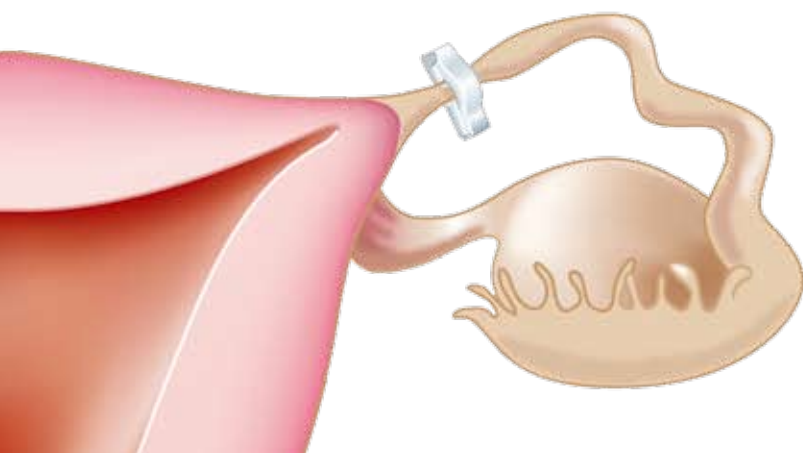


Kit 3: Single Use Filshie Kit - Elite



The Story So Far...

- For over 25 years more than 8 million Filshie Clips have been applied worldwide and are considered by many surgeons as the “Gold Standard” for female surgical contraception.
- The Filshie Clip has a proven long term success rate of 99.76%⁽⁴⁾.
- The Filshie Clip has an extremely low ectopic pregnancy rate – with just 4% of the 0.25% of failures resulting in an ectopic pregnancy⁽⁹⁾.
- The Filshie Clip System is a safe, simple and cost effective method for surgical contraception.
- Although female surgical contraception is considered permanent, the Filshie Clip procedure can be reversed with a very high success rate of 90%⁽¹⁰⁾.
- Recommended by the Royal College of Obstetricians and Gynaecologists in their Evidence-based Clinical Guideline Number 4, Male and Female Sterilisation⁽⁵⁾.



Simply
Beautiful...

Questions & Answers...

Can the Filshie Clip be applied under local anaesthetic?

- Yes. The Filshie Clip can be applied under local anaesthetic and the procedure is normally carried out as a day case, so an overnight stay in hospital is not necessary. The Royal College of Obstetricians and Gynaecologists state in their guidelines for Male and Female Sterilisation that *"the procedure should be performed as a day case, wherever possible"*⁽⁵⁾.

Is the procedure reversible?

- Although surgical contraception should be regarded as permanent, it is possible to have a Filshie Clip procedure reversed. This requires a surgical procedure where the fallopian tubes are re-joined. There is a very high chance of pregnancy after the reversal procedure with a clinically proven success rate of 90%⁽¹⁰⁾.

My doctor informs me that sterilisation has a failure rate of 1 in 200?

- This statistic is totally incorrect when referring to the Filshie Clip. The recognised failure rate for the Filshie Clip is 2.4 per 1,000⁽⁴⁾. The rate of 1 in 200 is based on data from a large American study called the CREST Study, which DID NOT include the Filshie Clip as it was not available in the USA at the time the study was being undertaken. It is incorrect and misleading to quote this failure rate when counselling on the Filshie Clip System.

Has the new disposable system been tried and tested?

- Yes. The product is routinely used in a number of hospitals throughout Europe and Australasia.

Do I need to re-train?

- No re-training is required. The loading process, closing mechanism and the Filshie Clips are all identical to the existing system.

How will I know the Filshie Clip is properly closed?

- A clear audible click is heard once full travel of the handle has been reached to indicate successful clip closure. However, just as before, clinical judgement and a visual inspection of the applied and closed clip should be used to check and confirm correct placement and closure of the clip.

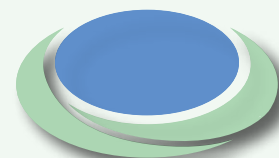
Product Code	Product Description
FE-7SS-500	Single Use Filshie Applicator *
FE-7SS-851	Single Use Filshie Kit – Standard
FE-7SS-854	Single Use Filshie Kit – Standard Plus 2
FE-7SS-852	Single Use Filshie Kit – Premium
FE-7SS-855	Single Use Filshie Kit – Premium Plus 2
FE-7SS-853	Single Use Filshie Kit – Elite
FE-7SS-856	Single Use Filshie Kit – Elite Plus 2
FE-10P-851	Filshie Clips – Box of 10 sterile pairs
FE-20P-851	Filshie Clips – Box of 20 sterile pairs *

* Export Markets Only

References:

- (1) Peterson HB, Xia Z, Hughes JM, Wilcox LS, Ratliff Tylor L, Trussell J. The risk of pregnancy after tubal sterilization: Findings for the US Collaborative Review of Sterilization. American Journal Obstetrics & Gynaecology, April 1996, 174:1161-1170 (CREST Study).
- (2) Penfield JA. The Filshie Clip for Female Sterilization: A Review of World Experience. Am. J. Obstet. Gynecol. (March 2000), 182-3, p485-489.
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- (4) Kovacs GT, Krins AJ. Female sterilisations with Filshie Clips: what is the risk failure? A retrospective survey of 30,000 applications. The Journal of Family Planning & Reproductive Health Care 2002; 28(1):34-5.
- (5) Royal College of Obstetricians and Gynaecologists. Evidence-based Clinical Guideline Number 4, Male and Female Sterilisation. January 2004.
- (6) Peterson HB, Xia Z, Hughes JM, Wilcox LS, Ratliff Tylor L, Trussell J. The risk of Ectopic Pregnancy after Tubal Sterilization: for The US Collaborative Review of Sterilization Working Group. The New England Journal of Medicine, 13 March 1997, Vol. 336(11):762-767.
- (7) FDA Advisory Panel Meeting. Presentation made by Prof. Theodore King, 26 Feb 1996.
- (8) NICE - Long-acting reversible contraception. Clinical Guideline 30, October 2006
- (9) Filshie GM. Long term experience with the Filshie Clip. Gynaecology Forum, Vol. 7, Issue 3, 2002.
- (10) Nwagbara PN, Stibbe HM, Browning AJ, Tonks AM. Reversal of female sterilisation experience in a district general hospital. Journal of Obstetrics and Gynaecology (1997), Vol. 17, No. 3, p.293-297.

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